GALGOTIAS UNIVERSITY

ADMISSION NUMBER												

School of Medical and Allied Sciences

Bachelor of Pharmacy
Mid Term Examination - Mar 2024

Duration : 90 Minutes
Max Marks : 30

Sem VIII - BPET8004 - Pharmaceutical Regulatory Science

General Instructions
Answer to the specific question asked
Draw neat, labelled diagrams wherever necessary
Approved data hand books are allowed subject to verification by the Invigilator

1)	Define generic drug.	K1	(2)
2)	Demonstrate drug discovery process.	K2	(2)
3)	Infer bioavailability.	K2	(2)
4)	What is lead optimization?	K1	(2)
5)	Infer toxicological studty.	K2	(2)
6)	Identify various aspects of innovator drugs.	K3	(5)
7)	Compare US FDA with CDSCO	K4	(5)
	OR		
	Compare ACTD with ICH-CTD.	K4	(5)
8)	Interpret the clinical phases of drug development.	K5	(10)
	OR		
	Access various phases of clinical trials.	K5	(10)